## R313. Environmental Quality, Radiation Control.

## R313-14. Violations and Escalated Enforcement.

# R313-14-1. Introduction, Purpose, and Authority.

- (1) The purpose of the radiation control inspection and compliance program is to assure the radiological safety of the public, radiation workers, and the environment by:
  - (a) ensuring compliance with Utah Radiation Control rules or license conditions;
  - (b) obtaining prompt correction of violations;
  - (c) deterring future violations; and
  - (d) encouraging improvement of licensee, permittee, or registrant performance, including the prompt identification, reporting, and correction of potential safety problems.
- (2) Consistent with the purpose of the radiation control inspection and compliance program, prompt and vigorous enforcement action shall be taken when dealing with licensees, permittees, or registrants who fail to demonstrate adherence to these rules. Enforcement action is dependent on the circumstances of the case and may require that discretion be exercised after consideration of these standards. Sanctions have been designed to ensure that a licensee, permittee, or registrant does not deliberately profit from violations of the Utah Radiation Control rules.
- (3) The rules set forth herein are adopted pursuant to the provisions of Subsections 19-3-103.5(1)(d), 19-3-104(4) and 19-3-104(8), 19-3-108, 19-3-109, and 19-3-111.

#### R313-14-3. Definitions.

As used in Rule R313-14, the following definitions apply:

- (1) "Material False Statement" means a statement that is false by omission or commission and is relevant to the regulatory process.
- (2) "Requirement" means a legally binding [requirement]mandate such as a statute, rule, license condition, permit, registration, technical specification, or order.
- (3) "Similar" means those violations which could have been reasonably expected to have been prevented by the licensee's, permittee's, or registrant's corrective action for a previous violation.
- (4) "Willfulness" means the deliberate intent to violate or falsify, and includes careless disregard for requirements. Acts which do not rise to the level of careless disregard are not included in this definition.

### R313-14-10. Severity of Violations.

- (1) Violations are placed in one of two major categories. These categories are:
  - (a) electronically produced radiation operations; or
  - (b) radioactive materials operations.
- (2) Regulatory requirements vary in public health and environmental safety significance. Therefore, it is essential that the relative importance of violations be identified as the first step in the enforcement process. Based upon their relative hazard, violations are assigned to one of five levels of severity.
- (3) Severity Level I is assigned to violations that are the most significant and Severity Level V violations are the least significant. In general, violations that are included in Severity Levels I

- and II involve actual or high potential impact on the public. Severity Level III violations are cause for significant concern. Severity Level IV violations are less serious but are of more than minor concern, however, if left uncorrected, they could lead to a more serious concern. Severity Level V violations are of minor safety or environmental concern.
- (4) The severity of a violation shall be characterized at the level best suited to the significance of the particular violation. A severity level may be increased if [the-]circumstances surrounding the violation involve careless disregard of requirements, deception, or other indications of willfulness. In determining the specific severity level of a violation involving willfulness, relevant factors will be considered, including [consideration will be given to factors like-]the position of the person involved in the violation, the significance of an underlying violation, the intent of the violator, and the economic advantage gained by the violation. The relative weight given to these factors in arriving at the appropriate severity level is dependent on the circumstances of the violation.
- (5) The severity level assigned to material false statements may be Severity Level I, II, or III, depending on the circumstances surrounding the statement. In determining the specific severity level of a violation involving material false statements or falsification of records, consideration is given to factors like the position of the person involved in the violation, for example, a first line supervisor as opposed to a senior manager, the significance of the information involved, and the intent of the violator. Negligence not amounting to careless disregard would be weighted differently than careless disregard or deliberateness. The relative weight given to these factors in arriving at the appropriate severity level is dependent on the circumstances of the violation.

### R313-14-15. Enforcement Actions.

This Section describes the enforcement sanctions available to the Director and specifies the conditions under which they are to be used.

- (1) Notice of Violation
  - (a) A Notice of Violation is a written notice setting forth one or more violations of a legally binding requirement. The <u>notice normally requires the</u> licensee, permittee, or registrant <u>may be required</u> to provide a written statement describing:
    - (i) corrective steps which have been taken by the licensee, permittee, or registrant and the results achieved;
    - (ii) corrective steps which shall be taken to prevent recurrence; and
    - (iii) the date when full compliance will be achieved.
  - (b) The Director may require responses to Notices of Violation to be under oath. [Normally, responses under oath may be required only in connection with civil penalties and orders.]
  - (c) A Notice of Violation is used by the Director as [the]a method for formalizing the existence of a violation. The Notice may be the only enforcement action taken or it may be used as a basis for other enforcement actions. Licensee, permittee, or registrant initiative for self-identification and correction of problems is encouraged. The Director shall not generally issue Notices of Violation for a violation that meets the five following tests:
    - (i) it was identified by the licensee, permittee, or registrant;
    - (ii) it fits in Severity Level IV or V;
    - (iii) it was reported, in writing, to the Director;

- (iv) it was or will be corrected, including measures to prevent recurrence, within [a reasonable time] 90 days; and
- (v) it was not a violation that could reasonably be expected to have been prevented by the licensee's, permittee's, or registrant's corrective action for a previous violation.
- (d) Licensees, permittees, or registrants are not ordinarily cited for violations resulting from matters outside of their control, like equipment failures that were not avoidable by reasonable quality assurance measures or management controls. [Generally however]However, licensees, permittees, and registrants are held responsible for [the lacts of their employees. Accordingly, the rules should not be construed to excuse personal errors.

## (2) Civil Penalty.

- (a) A civil penalty is a monetary penalty that may be imposed for violation of Utah Radiation Control Rules or lawful orders issued by the Director. Civil penalties are designed to emphasize the need for lasting remedial action and to deter future violations. Generally, civil penalties are imposed for Severity Level I and Severity Level II violations. [, are imposed for Severity Level II violations, in] In the absence of mitigating circumstances, civil penalties are considered for Severity Level III violations. [, and may be imposed] Penalities are not ordinarily imposed for Severity Level IV and V violations unless those violations [that] are similar to previous violations for which the licensee, permittee, or registrant failed to take effective corrective action.
- (b) The level of a civil penalty [is established so that a penalty does]may not exceed [\$5,000]\$10,000 per violation. Except as modified by provision of the next paragraphs, the base civil penalties are as follows:

#### **TABLE**

Severity Level I Violations	\$[ <del>5</del> ] <u>10</u> ,000
Severity Level II Violations	\$[4] <u>8</u> ,000
Severity Level III Violations	\$[ <del>2,5</del> ] <u>5,0</u> 00
Severity Level IV Violations	\$[ <del>-75</del> ] <u>1,50</u> 0
Severity Level V Violations	\$ [ <del>25</del> ] <u>50</u> 0

- (i) Comprehensive licensee, permittee, or registrant programs for detection, correction and reporting of problems that may constitute, or lead to, violation of regulatory requirements are important and consideration may be given for effective internal audit programs. When licensees, permittees, or registrants find, report, and correct a violation expeditiously and effectively, the Director may apply adjustment factors to reduce or eliminate a civil penalty.
- (ii) Ineffective licensee, permittee, or registrant programs for problem identification or correction are unacceptable. In cases involving willfulness, flagrant violations, repeated poor performance in an area of concern, or serious breakdown in management controls, the Director may apply the full enforcement authority.
- (iii) The Director may review the proposed civil penalty case on its own merits and adjust the civil penalty upward or downward appropriately. After considering the

relevant circumstances, adjustments to these values may be made for the factors identified below:

- (A) Reduction of the civil penalty may be given when a licensee, permittee, or registrant identifies the violation and promptly reports, in writing, the violation to the Director. No consideration will be given to this factor if the licensee, permittee, or registrant does not take immediate action to correct the problem upon discovery.
- (B) Recognizing that corrective action is always required to meet regulatory requirements, the promptness and extent to which the licensee, permittee, or registrant takes corrective action, including actions to prevent recurrence, may be considered in modifying the civil penalty to be assessed.
- (C) Reduction of the civil penalty may be given for prior good performance in the general area of concern.
- (D) The civil penalty may be increased as much as 50%, up to the \$10,000 maximum, for cases where the licensee, permittee, or registrant had prior knowledge of a problem as a result of an internal audit, or specific Director or industry notification, and had failed to take effective preventive steps.
- (E) The civil penalty may be increased as much as 50%, up to the \$10,000 maximum, where multiple examples of a particular violation are identified during the inspection period.
- (c) A violation of a continuing nature shall, for the purposes of calculating the proposed civil penalty, be considered a separate violation for each day of its continuance. A continuing violation is not considered a repeat violation. In the event a violation is repeated within five years, the scheduled amount of the civil penalty may be increased [25]50%, up to the \$10,000 maximum; and for repeat violations of Severity Levels II and III, the penalty [may]will not be avoided by compliance. Other rights and procedures are not affected by the repeat violation.
- (d) Payment of civil penalties shall be made within 30 working days of receipt of a Notice of Violation and Notice of Proposed Imposition of a Civil Penalty. An extension may be given when extenuating circumstances are shown to exist. Payment shall be made by check, payable to the Division of Radiation Control and mailed to the Division at the address shown with the Notice of Violation.

#### (3) Orders.

- (a) An Order is a written directive to modify, suspend, or revoke a license, permit, or registration; to cease and desist from a given practice or activity; to issue a civil penalty; or to take other action that may be necessary.
- (b) Modification Orders are issued when some change in licensee, permittee, or registrant equipment, procedures, or management control is necessary.
- (c) Suspension Orders may be used:
  - (i) to remove a threat to the public health and safety or the environment;
  - (ii) when the licensee, permittee, or registrant has not responded adequately to other enforcement action;
  - (iii) when the licensee, permittee, or registrant interferes with the conduct of an inspection; or

- (iv) for a reason not mentioned above for which license, permit, or registration revocation is authorized.
- (v) Suspensions may apply to all or part of the regulated activity. Ordinarily, an activity is not suspended, nor is a suspension prolonged for failure to comply with requirements when the failure is not willful or when adequate corrective actions have been taken.
- (d) Revocation Orders may be used:
  - (i) when a licensee, permittee, or registrant is unable or unwilling to comply with these rules;
  - (ii) when a licensee, permittee, or registrant refuses to correct a violation;
  - (iii) when a licensee, permittee, or registrant does not respond to a Notice of Violation;
  - (iv) when a licensee, permittee, or registrant does not pay a fee required by the Department; or
  - (v) for any other reason for which revocation is authorized.
- (e) Cease and Desist Orders are used to stop unauthorized activity that has continued despite notification by the Director that the activity is unauthorized.
- (f) Orders may be made effective immediately, without prior opportunity for hearing, whenever it is determined that the public health, interest, or safety so requires, or when the Order is responding to a violation involving willfulness. Otherwise, a prior opportunity for a hearing is afforded. For cases in which a basis could reasonably exist for not taking the action as proposed, the licensee, permittee, or registrant shall be afforded an opportunity to show cause why the Order should not be issued in the proposed manner.
- (4) Escalation of Enforcement Sanctions.
  - (a) In accordance with the provisions of Section 19-3-111 the radioactive material of a person may be impounded. Administrative procedures will be conducted as provided by Section R313-14-20, prior to disposal of impounded radioactive materials.
  - (b) Violations of Severity Levels I, II, or III are considered to be very serious. If repetitive very serious violations occur, the Director may issue Orders in conjunction with other enforcement actions to achieve immediate corrective actions and to deter their recurrence. In accordance with the criteria contained in this section, the Director shall carefully consider the circumstances of cases when selecting and applying the appropriate sanctions.
  - (c) The progression of enforcement actions for repetitive violations may be based on violations under a single license, permit, or registration. The actual progression to be used in a particular case may depend on the circumstances. When more than one facility is covered by a single license, permit, or registration, the normal progression may be based on repetitive violations under the same license, permit, or registration. It should be noted that under some circumstances, for example, where there is common control over some facet of facility operations, repetitive violations may be charged even though the second violation occurred at a different facility or under a different license, permit, or registration.
- (5) Related Administrative Actions.
  - (a) In addition to the formal enforcement mechanisms of Notices of Violation and Orders, the Director may use administrative mechanisms, like enforcement conferences,

bulletins, circulars, information notices, generic letters, and confirmatory action letters as part of the enforcement and regulatory program. Licensees, permittees, and registrants are expected to adhere to obligations and commitments resulting from these processes and the Director shall, if necessary, issue appropriate orders to make sure that expectation is realized.

- (b) Enforcement Conferences are meetings held by the Director with licensee, permittee, or registrant management to discuss safety, public health, or environmental problems, compliance with regulatory requirements, proposed corrective measures, including schedules for implementation, and enforcement options available to the Director.
- (c) Bulletins, Circulars, Information Notices, and Generic Letters are written notifications to groups of licensees, permittees, or registrants identifying specific problems and calling for or recommending specific actions on their part. Responses to these notifications may be required.
- (d) Confirmatory Action Letters are letters confirming a licensee's, permittee's, or registrant's agreement to take certain actions to remove significant concerns about health and safety, or the environment.

### R313-14-25. Public Disclosure of Enforcement Actions.

Enforcement actions and responses are publicly available for inspection. In addition, press releases are generally issued for Notices of Proposed Imposition of a Civil Penalty and Orders. In the case of orders and civil penalties related to violations at Severity Level I, II, or III, press releases may be issued at the time of the Order or the Notice of Proposed Imposition of the Civil Penalty. Press releases are not normally issued for Notices of Violation.